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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/510,596

Filed: 10/07/2004

1<sup>st</sup> Inventor: Masayuki II

For: Severe Sepsis Preventive Therapeutic Agent

Atty. Dkt. No. 3039 USOP

Art Unit: tba

Examiner: tba

Allowed:

Batch:

Paper No.:

**Response to Notice of Missing Requirements Under 35 USC §371**

MAIL STOP MISSING PARTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Notice of Missing Requirements mailed May 3, 2005, Applicants respectfully submit a true and correct copies of the executed declaration and assignment of the inventors, along with a copy of the Notice.

The Commissioner is authorized to charge the appropriate surcharge fees, and to credit any overpayment to our USPTO deposit account number 500799 for customer No. 23,115.

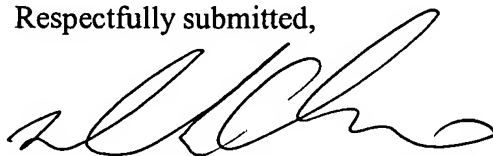
Early allowance of the claims is requested. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, the Examiner is respectfully invited to call applicants' attorney.

Respectfully submitted,

Dated: August 17, 2005

(847)383-3372

(847)383-3391



Mark Chao, Ph.D., Reg. No. 37,293

Elaine M. Ramesh, Ph.D., Reg. No. 43032


Attorney for Applicants

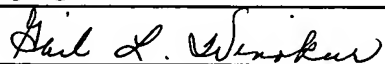
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|  |                      |                        |           |
|--|----------------------|------------------------|-----------|
| <b>TRANSMITTAL<br/>FORM</b>                              | Application Number   | 10/510,596             |           |
|  | Filing Date          | 10/07/2004             |           |
|  | First Named Inventor | Masayuki II            |           |
|  | Art Unit             | tba                    |           |
|  | Examiner Name        | tba                    |           |
| (to be used for all correspondence after initial filing) |                      |                        |           |
| Total Number of Pages in This Submission                 | 18                   | Attorney Docket Number | 3039 USOP |

| ENCLOSURES (Check all that apply)   |  |   |
|---|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input checked="" type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input checked="" type="checkbox"/> Reply to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts<br>under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a<br>Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board<br>of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC<br>(Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify<br>below):<br>Return Postcard;<br>Certificate of Express Mailing;<br>Executed Declaration and Assignment<br>Copy of Notification of Missing Requirement |
| Remarks<br>The Commissioner is hereby authorized to charge any additional fees which may be required,<br>or credit any overpayment to Deposit Account 500799.   |  |   |
| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT  |  |   |
| Firm Name   |  |   |
| Signature   |   |   |
| Printed name  | Mark Chao, Ph.D., JD   |   |
| Date  | 8/16/05  | Reg. No. 37,293   |

| CERTIFICATE OF TRANSMISSION/MAILING  |   |                |
|--|---|----------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with<br>sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on<br>the date shown below: <u>Express</u> |   |                |
| Signature  |  |                |
| Typed or printed name  | Gail L. Winokur   | Date 8/17/2005 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

# FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 1,150.00

## Complete if Known

Application Number 10/510,596  
 Filing Date 10/07/2004  
 First Named Inventor Masayuki II  
 Examiner Name tba  
 Art Unit tba  
 Attorney Docket No. 3039 USOP

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number 500799  
 Deposit Account Name Takeda Chemical Ind. Ltd.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity | Small Entity | Fee Code | Fee (\$) | Fee Description        | Fee Paid |
|--------------|--------------|----------|----------|------------------------|----------|
| 1001         | 2001         | 790      | 395      | Utility filing fee     |          |
| 1002         | 2002         | 350      | 175      | Design filing fee      |          |
| 1003         | 2003         | 550      | 275      | Plant filing fee       |          |
| 1004         | 2004         | 790      | 395      | Reissue filing fee     |          |
| 1005         | 2005         | 160      | 80       | Provisional filing fee |          |
| SUBTOTAL (1) |              |          |          |                        | (\$ )    |

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| Total Claims       | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Independent        | -20** =      | 18             |          |
| Multiple Dependent | -3** =       | 88             |          |
|                    |              | 300            |          |

| Large Entity | Small Entity | Fee Code | Fee (\$) | Fee Description  | Fee Paid |
|--------------|--------------|----------|----------|--|----------|
| 1202         | 2202         | 18       | 9        | Claims in excess of 20                                     |          |
| 1201         | 2201         | 88       | 44       | Independent claims in excess of 3                          |          |
| 1203         | 2203         | 300      | 150      | Multiple dependent claim, if not paid                      |          |
| 1204         | 2204         | 88       | 44       | ** Reissue independent claims over original patent         |          |
| 1205         | 2205         | 18       | 9        | ** Reissue claims in excess of 20 and over original patent |          |
| SUBTOTAL (2) |              |          |          |  | (\$ )    |

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity | Small Entity | Fee Code | Fee (\$) | Fee Description  | Fee Paid |
|--------------|--------------|----------|----------|--|----------|
| 1051         | 2051         | 130      | 65       | Surcharge - late filing fee or oath  | 130.00   |
| 1052         | 2052         | 50       | 25       | Surcharge - late provisional filing fee or cover sheet                     |          |
| 1053         | 2053         | 130      | 130      | Non-English specification  |          |
| 1812         | 2520         | 2,520    | 2,520    | For filing a request for ex parte reexamination                            |          |
| 1804         | 920*         | 1804     | 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805         | 1,840*       | 1805     | 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251         | 2251         | 110      | 55       | Extension for reply within first month                                     |          |
| 1252         | 2252         | 430      | 215      | Extension for reply within second month                                    |          |
| 1253         | 2253         | 980      | 490      | Extension for reply within third month                                     | 1,020.00 |
| 1254         | 2254         | 1,530    | 765      | Extension for reply within fourth month                                    |          |
| 1255         | 2255         | 2,080    | 1,040    | Extension for reply within fifth month                                     |          |
| 1401         | 2401         | 340      | 170      | Notice of Appeal   |          |
| 1402         | 2402         | 340      | 170      | Filing a brief in support of an appeal                                     |          |
| 1403         | 2403         | 300      | 150      | Request for oral hearing   |          |
| 1451         | 2451         | 1,510    | 1,510    | Petition to institute a public use proceeding                              |          |
| 1452         | 2452         | 110      | 55       | Petition to revive - unavoidable   |          |
| 1453         | 2453         | 1,330    | 665      | Petition to revive - unintentional   |          |
| 1501         | 2501         | 1,370    | 685      | Utility issue fee (or reissue)   |          |
| 1502         | 2502         | 490      | 245      | Design issue fee   |          |
| 1503         | 2503         | 660      | 330      | Plant issue fee  |          |
| 1460         | 2460         | 130      | 130      | Petitions to the Commissioner  |          |
| 1807         | 2807         | 50       | 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806         | 2806         | 180      | 180      | Submission of Information Disclosure Stmt                                  |          |
| 8021         | 28021        | 40       | 40       | Recording each patent assignment per property (times number of properties) |          |
| 1809         | 2809         | 790      | 395      | Filing a submission after final rejection (37 CFR 1.129(a))                |          |
| 1810         | 2810         | 790      | 395      | For each additional invention to be examined (37 CFR 1.129(b))             |          |
| 1801         | 2801         | 790      | 395      | Request for Continued Examination (RCE)                                    |          |
| 1802         | 2802         | 900      | 900      | Request for expedited examination of a design application                  |          |

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ ) 1,150.00

## SUBMITTED BY

Name (Print/Type) Mark Chao, Ph.D. JD Registration No. 37,293 Telephone 847-383-3372  
 Signature [Signature] (Attorney/Agent) Date 8/16/05

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Express Mail EV524905662 US



08-18-05 JC06 PCT/PTO 17 AUG 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/510,596

Filed: 10/07/2004

1<sup>st</sup> Inventor: Masayuki II

For: Severe Sepsis Preventive Therapeutic Agent

Atty. Dkt. No. 3039 USOP

Art Unit: tba

Examiner: tba

Allowed:

Batch:

Paper No.:

**CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10**

**USPS EXPRESS MAIL LABEL. No. EV 524905662 US**

**DATE IN: August 17, 2005**

**Itemized Papers/Items:**

1. This Certificate of Express Mailing and Return Postcard (2 pages)
2. Transmittal Form (1 page) and Fee Transmittal Form (1 page x 2)
3. Petition for Extension of Time (1 page X 2)
4. Response to Notice of Missing Requirements (1 page), and copy of Notification of Missing Requirements (2 pages)
5. Copy of executed Declaration (4 pages)
6. Copy of executed Assignment (2 pages), and Recordation Cover Sheet (1 page X 2)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

**MAIL STOP MISSING PARTS**

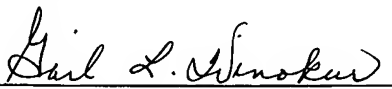
**Commissioner for Patents**

**P.O. Box 1450**

**Alexandria, VA 22313-1450**

on this date, 8/17/05

Dated: 8/17/05

  
Gail L. Winokur

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

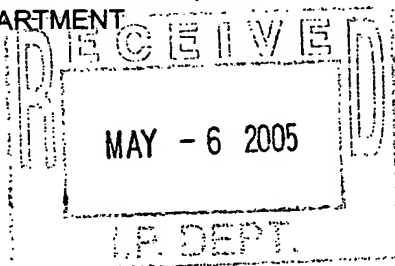


## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

|                             |                       |                  |
|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/510,596                  |                       | 3039 USOP        |

23115  
 TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
 INTELLECTUAL PROPERTY DEPARTMENT  
 475 HALF DAY ROAD  
 SUITE 500  
 LINCOLNSHIRE, IL 60069



|                               |               |
|-------------------------------|---------------|
| INTERNATIONAL APPLICATION NO. |               |
| PCT/JP03/04396                |               |
| I.A. FILING DATE              | PRIORITY DATE |
| 04/07/2003                    | 04/08/2002    |

CONFIRMATION NO. 1802  
 371 FORMALITIES LETTER  
  
 \*OC000000015920593\*

Date Mailed: 05/03/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 10/07/2004
- English Translation of the IA filed on 10/07/2004
- Copy of the International Search Report filed on 10/07/2004
- Copy of IPE Report filed on 10/07/2004
- Preliminary Amendments filed on 10/07/2004
- Information Disclosure Statements filed on 10/07/2004
- U.S. Basic National Fees filed on 10/07/2004
- Priority Documents filed on 10/07/2004

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE**

**DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

CHARITTA A BURT

Telephone: (703) 308-9140 EXT 207

**PART 1 - ATTORNEY/APPLICANT COPY**

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/510,596                  | PCT/JP03/04396                | 3039 US0P        |

FORM PCT/DO/EO/905 (371 Formalities Notice)